

Subpart B—[Reserved]

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 32081, June 4, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 466.1 Definitions.

As used in this part, unless the context indicates otherwise:

*Active staff privileges* means: (a) That a physician is authorized on a regular, rather than infrequent or courtesy, basis: (1) to order the admission of patients to a facility; (2) to perform diagnostic services in a facility; or (3) to care for and treat patients in a facility; or (b) that a health care practitioner other than a physician is authorized on a regular, rather than infrequent or courtesy, basis to order the admission of patients to a facility.

*Admission review* means a review and determination by a PRO of the medical necessity and appropriateness of a patient's admission to a specific facility.

*Continued stay review* means PRO review that is performed after admission review and during a patient's hospitalization to determine the medical necessity and appropriateness of continuing the patient's stay at a hospital level of care.

*Criteria* means predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of the quality, medical necessity, and appropriateness of a health care service may be compared.

*Diagnosis related group (DRG)* means a system for classifying inpatient hospital discharges. DRGs are used for purposes of determining payment to hospitals for inpatient hospital services under the Medicare prospective payment system.

*DRG validation* means a part of the prospective payment system in which a PRO validates that DRG assignments are based on the correct diagnostic and procedural information.

*Elective*, when applied to admission or to a health care service, means an admission or a service that can be delayed without substantial risk to the health of the individual.

*Five percent or more owner* means a person (including, where appropriate, a corporation) who:

- (a) Has an ownership interest of 5 percent or more;
- (b) Has an indirect ownership interest equal to 5 percent or more;
- (c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the

stock, or the profits of an entity) equal to five percent or more; or

(d) Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

*Health care facility* or *facility* means an organization involved in the delivery of health care services for which reimbursement may be made in whole or in part under Title XVIII of the Act.

*Health care practitioners other than physicians* means those health professionals who do not hold a doctor of medicine or doctor of osteopathy degree, who meet all applicable State or Federal requirements for practice of their professions, and who are in active practice.

*Hospital* means a health care institution or distinct part of a health care institution, as defined in Section 1861(e)-(g) of the Act, other than a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts.

*Initial denial determination* means an initial negative decision by a PRO, regarding the medical necessity, quality, or appropriateness of health care services furnished, or proposed to be furnished, to a patient.

*Major clinical area* means medicine, surgery, pediatrics, obstetrics and gynecology, or psychiatry.

*Major procedure* means a diagnostic or therapeutic procedure which involves a surgical or anesthetic risk or requires highly trained personnel or special facilities or equipment.

*Non-facility organization* means a corporate entity that (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities or association of facilities in the PRO area.

*Norm* means a pattern of performance in the delivery of health care services that is typical for a specified group.

*Norms* means numerical or statistical measures of average observed performance in the delivery of health care services.

*Outliers* means those cases that have either an extremely long length of stay or extraordinarily high costs when

compared to most discharges classified in the same DRG.

*Peer review* means review by health care practitioners of services ordered or furnished by other practitioners in the same professional field.

*Physician* means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery, or osteopathy. This includes medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

*Practitioner* means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

*Preadmission certification* means a favorable determination, transmitted to the hospital and the fiscal intermediary, approving the patient's admission for payment purposes.

*Preadmission review* means review prior to a patient's admission to a hospital to determine, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care.

*Preprocedure review* means review of a surgical or other invasive procedure prior to the conduct of the procedure.

*PRO review* means review performed in fulfillment of a contract with HCFA, either by the PRO or its subcontractors.

*Profile* means aggregated data in formats that display patterns of health care services over a defined period of time.

*Profile analysis* means review and analysis of profiles to identify and consider patterns of health care services.

*Quality review study* means an assessment conducted by or for a PRO of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

*Regional norms, criteria, and standards* means norms, criteria, and standards that apply to a geographic division which is larger than a PRO area.

*Retrospective review* means review that is conducted after services are

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provided to a patient. The review is focused on determining the appropriateness, necessity, quality, and reasonableness of health care services provided.

*Review responsibility* means (1) the responsibility of the PRO to perform review functions prescribed under Part B of Title XI of the Act and the Social Security Amendments of 1983 (Pub. L. No. 98-21) and the regulations of this part; (2) the responsibility to fulfill the terms and meet the objectives set forth in the negotiated contract between HCFA and the PRO; and (3) the authority of a PRO to make conclusive initial denial determinations regarding the medical necessity and appropriateness of health care and changes as a result of DRG validations.

*Skilled nursing facility (SNF)* means a health care institution or distinct part of an institution that (a) is primarily engaged in providing skilled nursing care or rehabilitative services to injured, disabled, or sick persons, and (b) has an agreement to participate in Medicare or Medicaid or both, and (c) is not a Christian Science sanatorium operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts.

*Standards* means professionally developed expressions of the range of acceptable variation from a norm or criterion.

*Subcontractor* means a facility or a non-facility organization under contract with a PRO to perform PRO review functions.

*Working day* means any one of at least five days of each week (excluding, at the option of each PRO, legal holidays) on which the necessary personnel are available to perform review.

[44 FR 32081, June 4, 1979, as amended at 45 FR 67545, Oct. 10, 1980; 46 FR 48569, Oct. 1, 1981. Redesignated and amended at 50 FR 15328, 15329, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986]

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### Subpart B—[Reserved]

### Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

SOURCE: 50 FR 15330, Apr. 17, 1985, unless otherwise noted.

#### GENERAL PROVISIONS

#### § 466.70 Statutory bases and applicability.

(a) *Statutory basis.* Sections 1154, 1866(a)(1)(F) and 1886(f)(2) of the Act require that a PRO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary. Section 1154(a)(4) of the Act requires PROs, or, in certain circumstances, non-PRO entities, to perform quality of care reviews of services furnished under risk-basis contracts by health maintenance organizations (HMOs) and competitive medical plans (CMPs) that are covered under subpart C of part 417 of this chapter.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a PRO and its subcontractors. Section 466.72 of this part also applies, for purposes of quality of care reviews under section 1154(a)(4) of the Act, to non-PRO entities that enter into contracts to perform reviews of services furnished under risk-basis contracts by HMOs and CMPs under subpart C of part 417 of this chapter.

[52 FR 37457, Oct. 7, 1987]

#### § 466.71 PRO review requirements.

(a) *Scope of PRO review.* In its review, the PRO must determine (in accordance with the terms of its contract)—

(1) Whether the services are or were reasonable and medically necessary for the diagnosis and treatment of illness or injury or to improve functioning of